IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	C.A. No. 18-823-CFC
Plaintiffs,	)	[redacted]
v.	)	
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

PAR'S CONCISE COUNTER-STATEMENT OF FACTS IN OPPOSITION TO EAGLE'S CONCISE STATEMENT OF UNDISPUTED FACTS [D.I. 177]

Par responds to Eagle's Concise Statement of Facts ("E-CSOF") as follows:

TABLE OF EXHIBITS[1]

Exhibit No.	Description
A	Module 3.2.P.8.2 Post-Approval Stability Commitment for ANDA No. 211538 (EAGLEVAS0047249)
B	Field Alert Report Submission, Questions and Answers, Draft FDA Guidance for Industry (July 2018)
C	Module 3.2.P.8.1 Stability Summary and Conclusions for ANDA No. 211538 (EAGLEVAS047328)
D	Module 3.2.P.3.2 Manufacturing Process Development for ANDA No. 211538 *excerpts* (EAGLEVAS0000670)
E	[redacted] (AMRIVAS0114545)
F	Project Notebook, SVA001/002/003, pH data records (AMRIVAS011554)
G	Stability Data for SVA001 submitted with ANDA No. 211538 (EAGLEVAS0047274)
H	Opening Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement (*excerpts*), dated November 15, 2019.
I	Reply Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement (*excerpts*), dated January 20, 2020.
J	Supplemental Expert Report of Lee E. Kirsch, Ph.D. Regarding Infringement, dated May 8, 2020.
K	Vasopressin Injection, USP Stability Analysis; A Statistical Evaluation of pH, submitted with ANDA No. 211538 (EAGLEVAS0047242)
L	Module 3.2.P.5.1 Specifications for ANDA No. 211538 (EAGLEVAS0046173)
M	Excerpts from October 9, 2019, Deposition of James Romito.
N	Excerpts from Executed Batch Record for SVA008, submitted with ANDA No. 211538 (EAGLEVAS0048569)

[1] Exhibits are attached to the Declaration of Brian Goldberg.

RESPONSES TO EAGLE'S STATEMENT OF ASSERTED FACTS

PAR'S VASOSTRICT® PRODUCT

1. In April 2014, Par received FDA approval for its original Vasostrict® product, which was made with a pH of 3.4-3.6. (Ex. 1 at PAR-VASO_0015573, 581, 586.)

RESPONSE:

Undisputed.[2]

2. In March 2016, Par received FDA approval for a reformulated Vasostrict® product, which is made with a pH of 3.8. (Ex. 2 at PAR-VASO 0014542-43, 545.)

RESPONSE:

Undisputed.

THE PATENTS-IN-SUIT

3. For purposes of trial, Par asserts that Eagle's ANDA product will literally infringe claim 13 of U.S. Patent 9,687,526 ("'526 Patent"); claims 1, 3-5, and 7 of U.S. Patent 9,744,209 ("'209 Patent"); and claims 1, 4, 5, and 8 of U.S. Patent 9,750,785 ("'785 Patent") ("Patents-in-Suit"). (Ex. 3.)

RESPONSE:

Undisputed.

4. Claim 13 of the '526 patent requires a vasopressin formulation having a pH of 3.8. (Ex. 4, claims 1, 13.)

[2] "Undisputed" means that Par does not dispute Eagle's assertion for purposes of opposing Eagle's request, and the Court may consider it undisputed in ruling upon that request and any subsequent motion for summary judgment, if leave is granted. Par does not admit its truth for any other purpose.

RESPONSE:

Undisputed (requires administration of such a formulation).

5. Each asserted claim of the '209 and '785 patents requires a vasopressin formulation having a pH of 3.7-3.9. (Ex. 5, claim 1; Ex. 6, claim 1.)

RESPONSE:

Undisputed (requires the manufacture, sale, or use/administration of such a formulation).

6. Par contends that the Patents-in-Suit cover reformulated Vasostrict®, but not original Vasostrict®. (Ex. 7; Ex. 8.)

RESPONSE:

Partially disputed-the cited documents state that Par was not contending that the Patents-in-Suit cover original Vasostrict.

THE ANDA PROCESS

7. The Hatch-Waxman Act allows for the filing of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of an approved drug product, without separately establishing safety and efficacy. 21 U.S.C. § 355(j).

RESPONSE:

Legal conclusion-undisputed.

8. If a proposed generic product is rated "Q1/Q2" to an approved product, the FDA has determined that it is qualitatively and quantitatively the same as the approved product, and will not require separate bioequivalence studies. 21 CFR § 320.22(b)(1); *see also id*. § 314.94(a)(9)(iii).

RESPONSE:

Legal conclusion-incomplete.

9. The ANDA specifies the formulation and properties of the proposed generic product that will be marketed by the applicant, and provides specifications for parameters such as pH and impurities in accordance with good manufacturing practices. *Id*. § 314.94(a)(5)—(7), (9); *see also* § 314.50(d)(1)(i)—(ii); *see generally* 21 CFR § 211 *et seq*. (Current Good Manufacturing Practices For Finished Pharmaceuticals).

RESPONSE:

Legal conclusion-incomplete.

10. Manufacturing specifications define properties the product must have during specific steps in the manufacturing process. *Id*. § 211.110(a)—(c). "Release" specifications define properties the product must have on release from manufacturing. *Id*. § 211.165(a), (c)-(f). "Stability" specifications define properties the product must have after release and through its shelf life. *Id*. § 211.166(a).

RESPONSE:

Legal conclusions-partially disputed.

Release specifications: FDA regulations state that "[f]or each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product . . . prior to release" and that products that fail to meet the release specifications "shall be rejected." 21 CFR 211.165(a), (f). The converse is also true—drug products meeting those specifications may be released for commercial sale. *Id*.

Stability specifications: Stability specifications are "used in determining appropriate storage conditions and expiration dates." *Id*. § 211.166(a). Once commercial production begins, samples of products sold are tested after-the-fact to determine whether they remain within specification. *See* Ex. A [redacted]

[redacted]. If the manufacturer finds a commercially-sold product that fell out-of-specification, it must submit a "Field Alert Report" ("FAR") to FDA. 21 CFR 314.81; Ex. B (Draft FDA Guidance). In such instances, the product need not be recalled. *See* Ex. A [redacted]; *United States v. Gilead Scis., Inc.*, 2019 WL 5722618, at *6 (N.D. Cal. Nov. 5, 2019); *Oregon ex rel. Kroger v. Johnson & Johnson*, 832 F. Supp. 2d 1250, 1252–53 (D. Or. 2011).

11. An ANDA applicant must conduct stability studies demonstrating that its proposed ANDA product will meet its specifications over its shelf life. *Id.* § 211.166. In such studies, the product may be stored under various conditions and appropriate measurements taken at regular intervals during the product's shelf life, which are reported to the FDA. *Id.* § 211.166(b).

RESPONSE:

Disputed. *See supra* E-CSOF 10.

12. Once its ANDA is approved, a generic manufacturer may not market a product that does not comply with its ANDA specifications, without being subject to strict sanctions. *See, e.g.*, 21 U.S.C. §§ 331(d), 332(a), 333(a), 334(a)(1), 335b(a)(1), 335c(a)(1).

RESPONSE:

Disputed. Sanctions do not apply to after-the-fact out-of-specification stability results encountered in the field; they only trigger FDA reporting and consultation processes. *See supra* E-CSOF 10.

EAGLE'S ANDA PRODUCT

Background

13. On March 23, 2018, Eagle's ANDA 211538 was accepted for filing by the FDA. (Ex. 9 at EAGLEVAS0000013.) [redacted]

RESPONSE:

Undisputed.

14. [redacted]

RESPONSE:

Disputed-final determination not yet made.

15. [redacted]

RESPONSE:

Undisputed.

Eagle's ANDA pH Specifications

16. [redacted]

RESPONSE:

Undisputed-with customary rounding, the upper-limit is [redacted]

[redacted]

Ex. C, EAGLEVAS0047336.

17. [redacted]

RESPONSE:

Disputed. *See supra* E-CSOF 10; Par's SAF below.

Stability Testing of Eagle's ANDA Product

18. With its ANDA, Eagle was required to submit results of stability testing of samples of its ANDA product to the FDA. 21 CFR § 211.166.

RESPONSE:

Undisputed.

19. [redacted]

RESPONSE:

Disputed. [redacted]

[redacted]

20. [redacted]

RESPONSE:

Undisputed.

21. [redacted]

RESPONSE:

Disputed. [redacted]

22. [redacted]

RESPONSE:

Undisputed.

23. [redacted]

RESPONSE:

Disputed. [redacted]

24. [redacted]

RESPONSE:

Undisputed.

25. [redacted]

RESPONSE:

Disputed. Eagle mischaracterizes [redacted] (*see supra* E-CSOF 23).

26. [redacted]

RESPONSE:

Disputed. *See supra* E-CSOF 23-25.

27. [redacted]

RESPONSE:

Disputed. Eagle over-states [redacted] (*see supra* E-CSOF 23) and fails to note that [redacted].

28. [redacted]

RESPONSE:

Disputed. *See supra* E-CSOF 23. It is undisputed that [redacted] *See* Statement of Additional Facts ("Par's SAF") ¶7 below. [redacted]. *Id.*, ¶¶8-9. [redacted]. *Id.*, ¶¶10-14.

29. [redacted]

RESPONSE:

Disputed. *See supra* E-CSOF 23-28.

30. [redacted]

RESPONSE:

Disputed. There were [redacted] Ex. E, AMRIVAS0114545.

31. [redacted]

RESPONSE:

Disputed. [redacted]. *Id.*

32. P[redacted]

RESPONSE:

Disputed. There were [redacted] (*id.*), and Dr. Kirsch's opinions are based on additional evidence cited in his reports. Par's SAF ¶¶6-13.

33. [redacted]

RESPONSE:

Undisputed-[redacted] *See* Par's SAF.

[redacted]

34. [redacted]

RESPONSE:

Undisputed.

35. [redacted]

RESPONSE:

Undisputed.

36. [redacted]

RESPONSE:

Undisputed.

[redacted]

37. [redacted]

RESPONSE:

Undisputed.

38. [redacted]

RESPONSE:

Undisputed.

39. [redacted]

RESPONSE:

Undisputed.

40. [redacted]

RESPONSE:

Undisputed.

41. [redacted]

RESPONSE:

Undisputed.

42. [redacted]

RESPONSE:

Disputed. Eagle misleadingly mischaracterizes [redacted]

[redacted]

RESPONSE:

Undisputed.

44. [redacted]

RESPONSE:

Undisputed-*but see* Par's SAF ¶¶14-19.

STATEMENT OF ADDITIONAL MATERIAL FACTS

EAGLE'S INFRINGEMENT

1. [redacted]

2. [redacted].

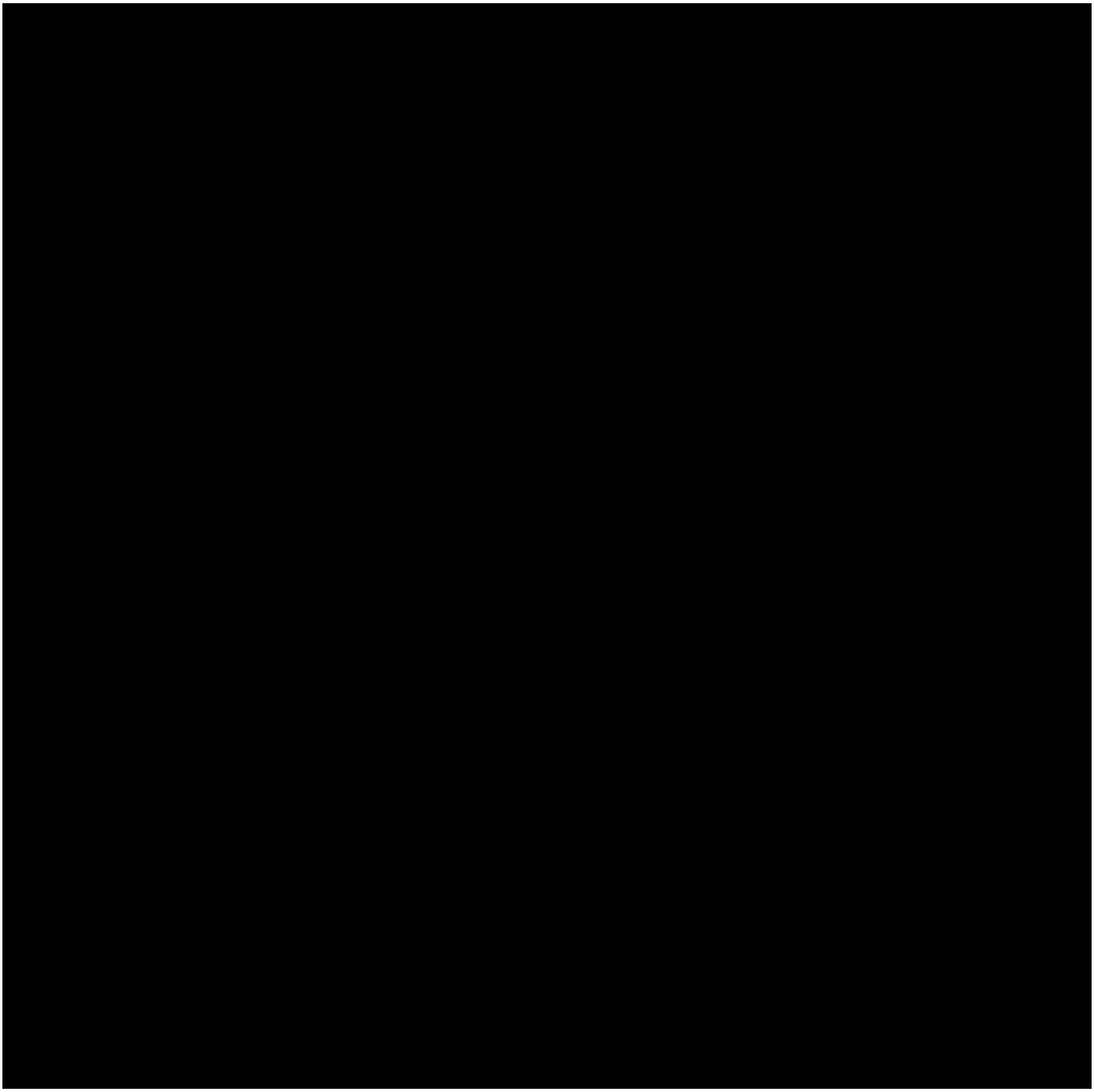
3. [redacted]

4. The commercial sale of products [redacted] and the administration of such products to patients in accordance with Eagle's proposed labeling, would therefore infringe the Patents-in-Suit. Ex. H (Kirsch Opening), ¶¶ 65-67, 110, 157; Ex. I (Kirsch Reply), ¶¶17-46, 68-70.

5. If FDA approves Eagle's ANDA, Eagle will be authorized to sell products [redacted], and hence, it can be expected that, [redacted], the commercial sale and use of such products would infringe Par's patents. *See id.*; 35 U.S.C. § 271(a) (it is an act of infringement to make, ***use***, ***sell or offer to sell*** a patented inventions).

THERE IS NO ANOMALY

6. [redacted]



7. [redacted]

8. [redacted]

9. [redacted]

10. [redacted].

11. [redacted]

[redacted]

12. [redacted]

[redacted]

[redacted]

[redacted]3.

13. [redacted]

[redacted]

- [redacted]
- [redacted]
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14. [redacted]

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[redacted]

[redacted]

[redacted]

15. [redacted]

16. [redacted]

17. [redacted]

18. [redacted]

[redacted]

19. [redacted]

[redacted]

[redacted]

Dated: May 8, 2020

Respectfully submitted,

FARNAN LLP

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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of the Court's November 6, 2019 Standing Order and April 9, 2020 Oral Order. The text of this document was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, this document contains 1,634 words, excluding tables, headings, and the repetition of Eagle's statements.

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Dated: May 8, 2020